

## REMARKS

In accordance with the foregoing, claim 13 has been amended. Claims 1-6, 13-19 and 24 are pending and claims 13-15 and 24 are under consideration.

Claim 13 has been amended to recite that the starch raw material is heat treated to a temperature of 100 to 130°C using compressed steam at a temperature of at least 120°C. Antecedent support can be found, for example, in the previous version of claim 13 and in Examples 2-5 of the present application.

### **Claims 13-15 and 24 are rejected under 35 U.S.C §103(a)**

Claims 13-15 and 24 are rejected under 35 U.S.C §103(a) as being unpatentable over US 5,759,581 to Baensch et al. (hereafter Baensch) in view of WO 00/40617 to Van Soest et al. (hereafter Van Soest) and US 6,822,091 to Kesselmans et al. (hereafter Kesselmans).

Amended claim 13 recites that the starch raw material is heat treated using compressed steam at a temperature of at least 120°C. Baensch discloses a multistage processing for raw starch, but does not disclose that the raw starch is heated with compressed steam. Van Soest and Kesselmans do not compensate for the deficiency of Baensch.

Claim 13 also recites that "the functional starch powder has a water retention capacity of 400% or more, a collapse time of 5 hr or more, and a gel indentation load of 200 g or more." As described in paragraph [0058] of the published application US 2006/0204569 (below), if the retention capacity is below 400%, when the starch is hydrated, it may not form a gel, causing tablets formed therefrom to disintegrate. Alternatively, if the starch powder *does* form a gel, the active ingredient may be rapidly diffused. A high water retention capacity, on the other hand, results in good gel properties.

#### US 2006/0204569

[0058] The functional starch powder of the invention should have a water retention capacity of 400% or more, more preferably 500% or more, particularly preferably 700%. The term "water retention capacity" is defined as the volume of pure water retained by starch after the centrifugation (2000G, 10 minutes) of a dispersion of 1 g of dry starch powder in pure water. When the water retention capacity is less than 400%, the starch powder is hydrated to form no gel, resulting in disintegration of tablets, or the starch powder cannot exhibit satisfactory release-sustaining properties because of rapid diffusion of an active ingredient(s) even when the starch powder forms a gel layer. The gel-forming capability is enhanced with an increase of the water retention capacity. When the water retention capacity is high, the gel is desirably not destroyed even at a high

ionic strength, though the maximum water retention capacity is dependent on characteristics of a starch raw material and is at most 3000%.

Baensch does not disclose a functional starch powder having a water retention capacity of 400% or more. The rejection takes the position that Baensch produces a functional starch by a similar method, and thus the same results would occur, meaning that the final starch would have a similar retention capacity as that claimed. However, this position is not supported by the art. Baensch describes at column 2, lines 47-53 that the functional starch produced in the reference is resistant to swelling in an aqueous medium. If Baensch used a similar process to produce its functional starch as the present invention (it does not), similar results might occur. However, Baensch states that its starch is resistant to swelling. The present invention is opposite to Baensch. Claim 13 recites that the functional starch powder has a water retention capacity of 400% or more. Baensch uses a different method and produces different results.

Baensch does not disclose or suggest a heat treating step performed using compressed steam and does not disclose or suggest a functional starch powder having a water retention capacity of 400% or more. Neither Van Soest nor Kesselmans compensate for the deficiency in Baensch. Accordingly, the rejection should be withdrawn.

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action, to that effect, is courteously solicited.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned to attend to these matters.

If there are any additional fees associated with filing of this Amendment, please charge the same to our Deposit Account No. 19-3935.

Respectfully submitted,

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